

Art 34

We claim:

1. A medical device for placement within a portion of a mammalian patient, the device comprising a tubular member formed from a substantially rigid material having a hardness of between approximately 30° Shore-A and approximately 70° Shore-A, said tubular member having a distal end and a proximal end and extending longitudinally there between, forming a lumen there through, wherein said tubular member is substantially non-cylindrical at said proximal end.
2. The medical device of claim 1, wherein the substantially rigid material has a hardness of between approximately 40° Shore-A and approximately 60° Shore-A.
3. The medical device of claim 1, wherein the substantially rigid material has a hardness of between approximately 45° Shore-A and approximately 55° Shore-A.
4. The medical device of claim 1, wherein the substantially rigid material has a hardness of approximately 50° Shore-A.
5. The medical device of claim 1, wherein said substantially rigid material is silicone.
6. The medical device of claim 1, wherein said proximal end is closed.
7. The medical device of claim 1, wherein said proximal end is open.
8. The medical device of claim 1, wherein said tubular member comprises a first portion comprising the proximal end of said tubular member, a second portion comprising the distal end of said tubular member, and a connecting bend formed at a junction of said first portion and said second portion, wherein said first portion is substantially non-cylindrical and wherein said connecting bend forms an oblique angle between said first portion and said second portion, said connecting bend being closer to the proximal end of said tubular member relative to the distal end of said tubular member.
9. The medical device of claim 8, wherein said angle is between about 90 degrees and about 180 degrees.
10. The medical device of claim 8, wherein said angle is between about 120 degrees and about 150 degrees.
11. The medical device of claim 8, wherein said angle is about 130 degrees.

12. The medical device of claim 1, wherein said tubular member has an outer diameter between about 3 mm and about 20mm.
13. The medical device of claim 12, wherein said outer diameter is between about 6 mm and about 15 mm.
14. The medical device of claim 12, wherein said outer diameter is selected from the group consisting of about 6 mm, about 7 mm, about 8 mm, about 9 mm, about 10 mm, about 11 mm, about 12 mm, about 13 mm, about 14 mm, and about 15mm.
15. The medical device of claim 1, further comprising a substantially L-shaped tracheotomy connector member, said connector member being operably connected to said tubular member.
16. The medical device of claim 1, further comprising a fixation member, said fixation member being substantially flexible, said fixation member being operably connected to said tubular member.
17. The medical device of claim 1, wherein said fixation member is a inner silicone tongue.
18. The medical device of claim 1, wherein said proximal end of said tubular member has a larger outer diameter than said distal end of said tubular member.
19. The medical device of claim 1, further comprising a substance capable of being released in a controlled manner from said device, said substance selected from the group consisting of a polypeptide growth factor, a hormone, an anti-inflammatory agent, and an anti-scar formation compound.
20. The medical device of claim 1, further comprising an anti-microbial agent.
21. The medical device of claim 1, wherein said device is substantially similar to the inner laryngotracheal contours of a human.
22. The medical device of claim 1, wherein said device is formed in the shape of a human larynx.
23. A method of treating a laryngotracheal stenosis, comprising:
endoscopically inserting a medical device into the larynx of a mammalian patient suffering therefrom, said medical device comprising a tubular member formed from a substantially rigid material having a hardness of between approximately 30°

Shore-A and approximately 70° Shore-A, said tubular member having a distal end and a proximal end and extending longitudinally there between, forming a lumen there through, wherein said tubular member comprises a first portion comprising the proximal end of said tubular member, a second portion comprising the distal end of said tubular member, and a connecting bend formed at a junction of said first portion and said second portion, wherein said first portion is substantially non-cylindrical and, wherein said connecting bend forms an oblique angle between said first portion and said second portion, said connecting bend being closer to the proximal end of said tubular member relative to the distal end of said tubular member, such that said connecting bend of said tubular member contacts the arytenoid cartilage of said patient, thus maintaining the appropriate interarytenoid distance,

such that the laryngotracheal stenosis is treated upon insertion.

24. The method of claim 23, wherein said laryngotracheal stenosis is a supraglottic, glottic, subglottic or upper tracheal stenosis.
25. The method of claim 23, wherein the proximal end of the tubular member is closed.
26. The method of claim 23, wherein the proximal end of the tubular member is open.
27. The method of claim 23, wherein said medical device further comprises:
 - a substantially flexible fixation member, wherein said fixation member has a proximal end and a distal end, said proximal end being operably connected to said tubular member, and
 - a substantially L-shaped tracheotomy connector member,whereby said method further comprises:
 - drawing the distal end of said fixation member through a tracheostoma of said patient and fixing said distal end to a fixation means; and
 - operably connecting said connector member to said tubular member.
28. The medical device of claim 8, wherein said angle is about 155 degrees.

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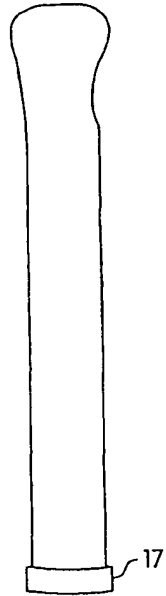


Fig. 1A

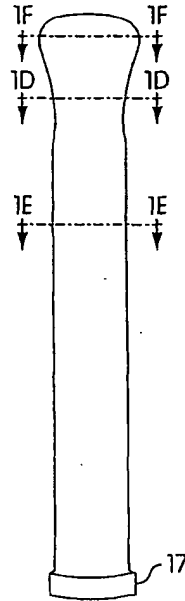


Fig. 1B

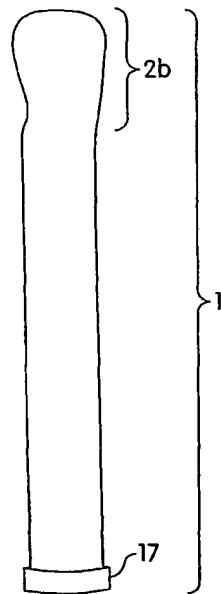


Fig. 1C



Fig. 1D



Fig. 1E

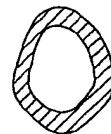


Fig. 1F

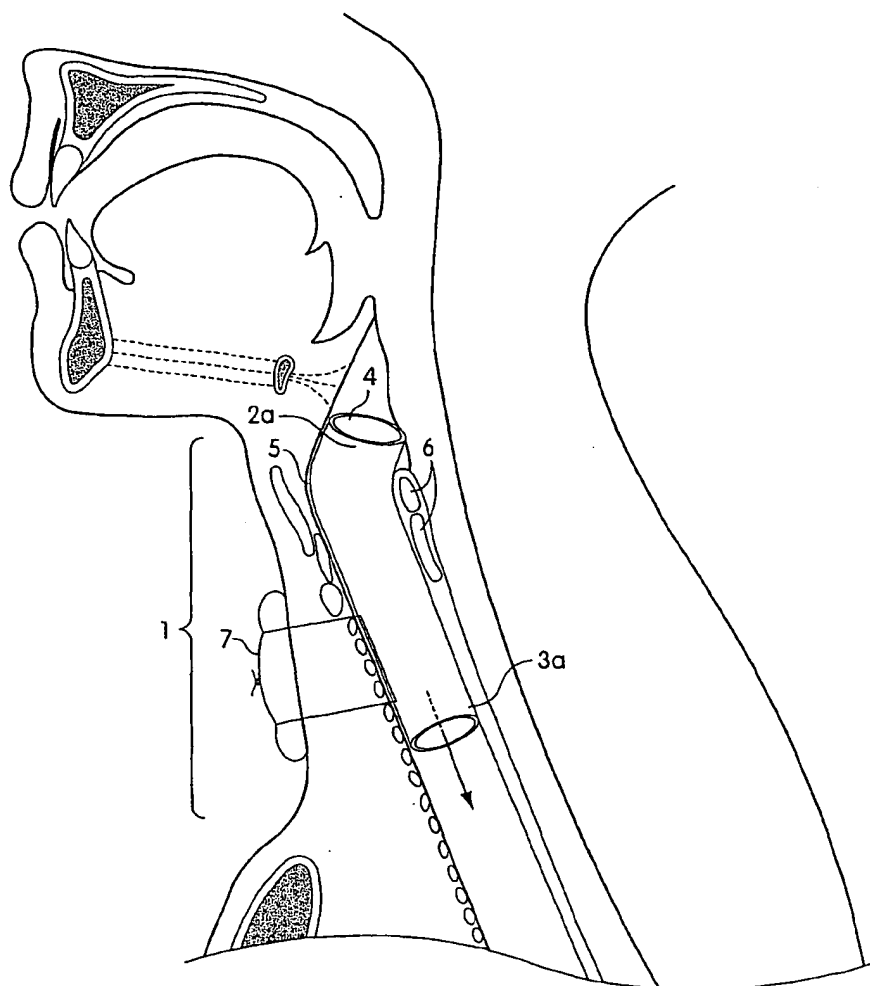


Fig. 2

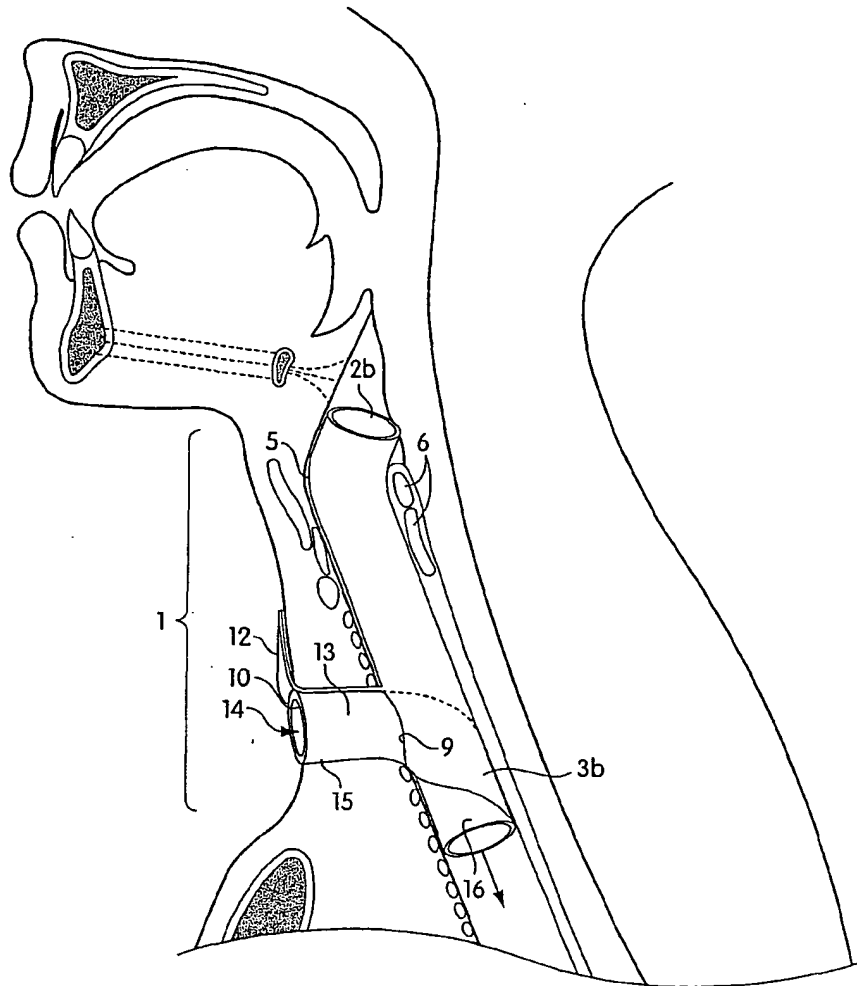


Fig. 3

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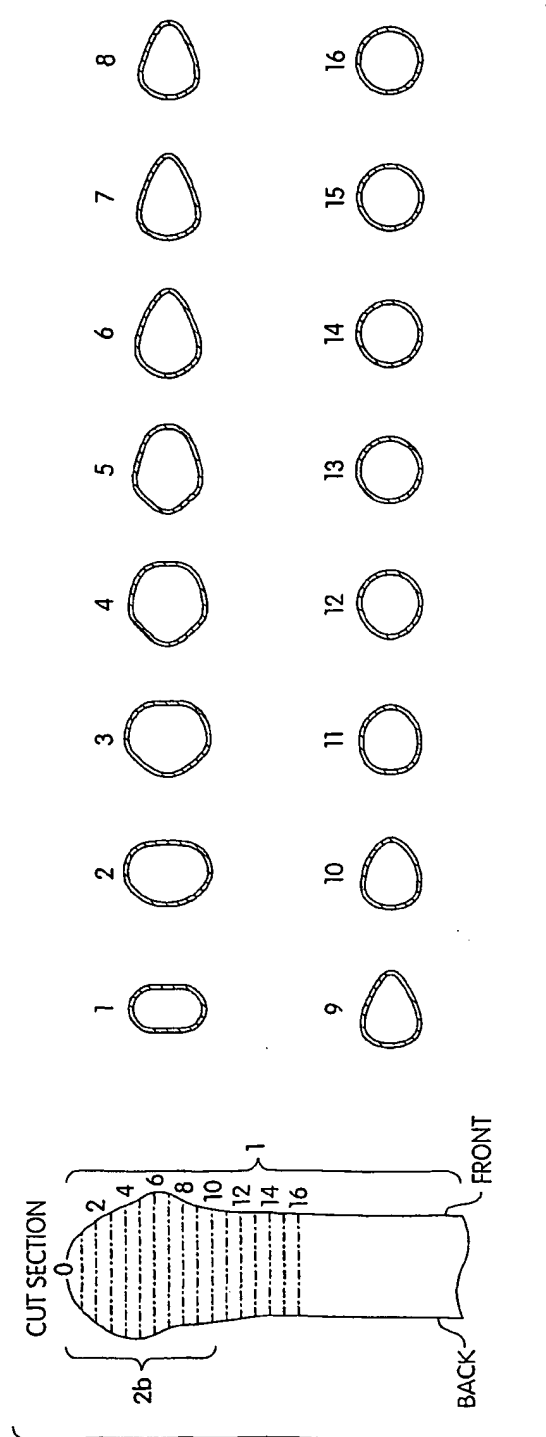


Fig. 4

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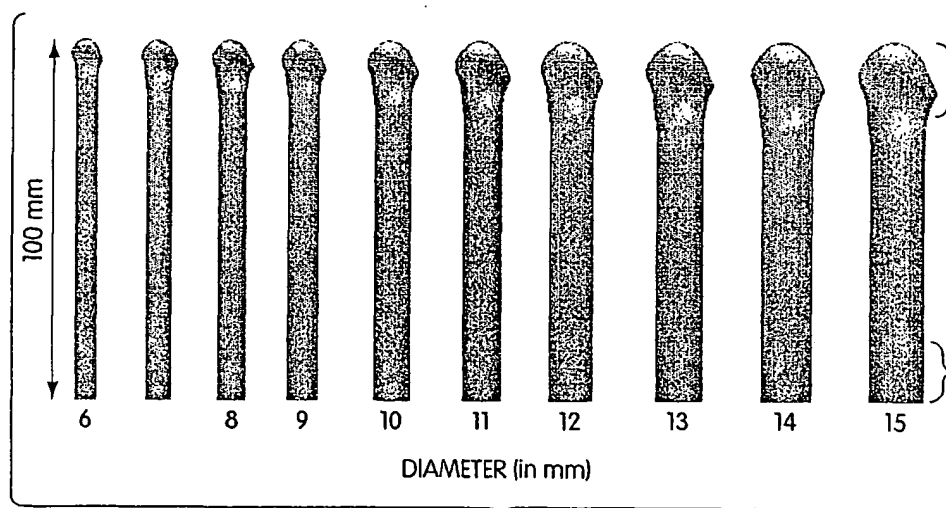


Fig. 5

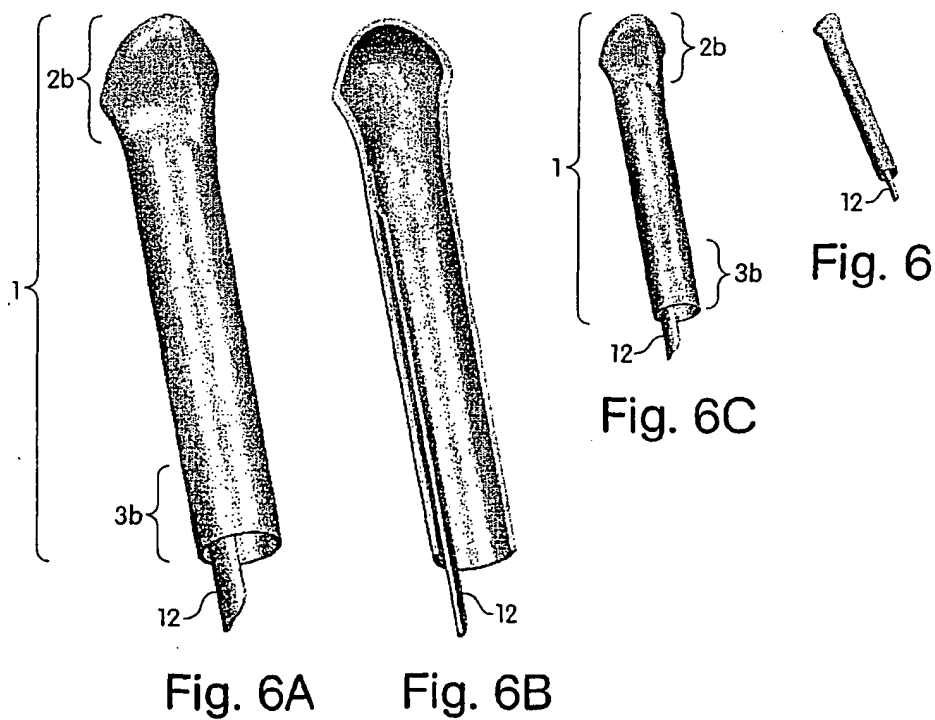


Fig. 6A

Fig. 6B

Fig. 6C

Fig. 6

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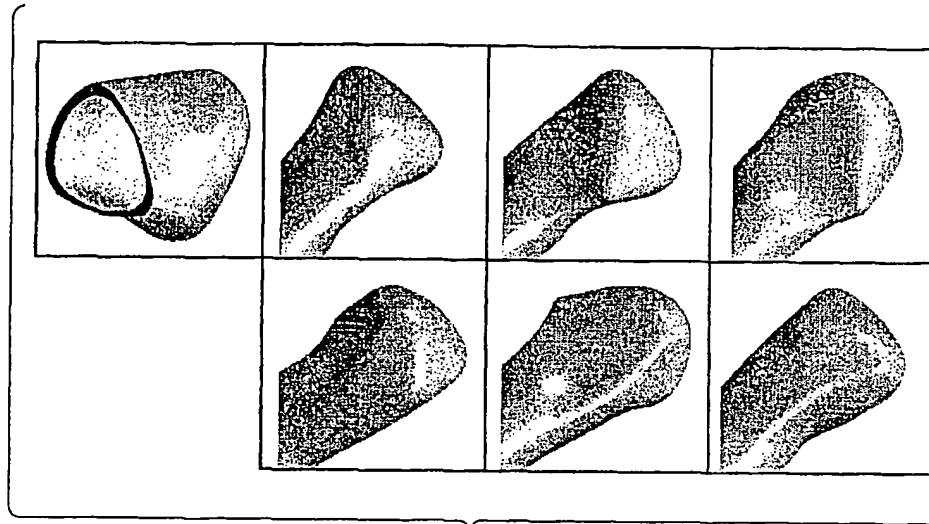


Fig. 7

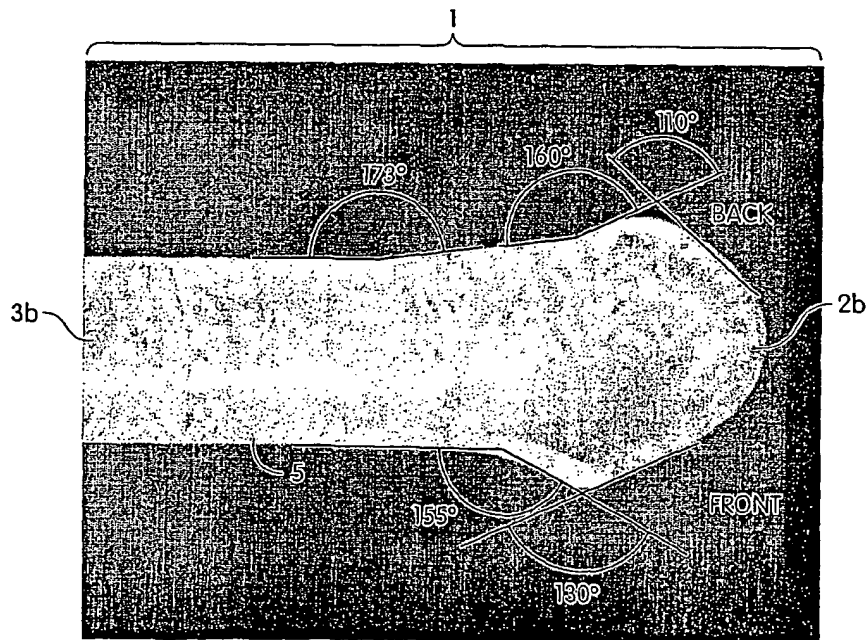


Fig. 8